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Improving diarrhoea management in children through the development of rotavirus diarrhoea diagnostic kits and viral diarrhoea awareness to reduce diarrhoea illness and death

Submission date
18/05/2022

Recruitment status
No longer recruiting

Registration date
10/06/2022

Overall study status
Completed

Last Edited
26/09/2025

Condition category
Infections and Infestations

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
Diarrhoea causes illness and death in many children below 5 years old worldwide but about 90% of these sicknesses and death occur in Asia and Africa. In Nigeria, a lot of children die of diarrhoea. A virus called rotavirus is the major microorganism (or pathogen) causing diarrhoea in children but in Nigeria and many African countries, this virus is not usually diagnosed when they bring children to the hospital for diarrhoea. This is because the available tests that can detect the virus (PCR or ELISA) are time-consuming, requires the training of staff and big equipment and are also expensive. This affects the proper management of children having diarrhoea as almost all the children are given antibiotics. One way to reduce the unnecessary use of antibiotics and to help in the proper management of diarrhoea in children in low-income countries is to develop a quick, easy to perform and cheap kit that can detect rotavirus. No one knows if the developed kit will work well like PCR and ELISA when children have diarrhoea. This study aims to develop the kit and compare if it works well like PCR and ELISA by using the three kits to detect rotavirus in the stool of children with diarrhoea and those without diarrhoea to avoid false-positive results. The goal is to make available a quick, bedside, easy to perform and cheap rotavirus kit in poor countries and also to check the factors responsible for contracting diarrhoea and having severe diarrhoea in children using a questionnaire. The findings of this study should help to improve diarrhoea management thereby reducing deaths due to diarrhoea in children and reducing the unnecessary use of antibiotics in children.

Who can participate?
Children aged from 0 to 60 months who have diarrhoea and healthy children in the same age group who will serve as a control group

What does the study involve?
Parents who come to the hospital with their child/children having diarrhoea and those who come for immunization only are asked to agree on behalf of their children that their children could join the study. The children having diarrhoea are the cases while healthy children without diarrhoea

who come for immunization are the controls. Stool samples will be collected from both groups and they will fill out questionnaires. The presence or absence of rotavirus in the stool will be tested in the laboratory.

What are the possible benefits and risks of participating?
The parent, guardian or caregiver will be informed about rotavirus and the importance of personal hygiene for its prevention. The test result will also be provided at no cost to interested parents. Indirect benefits will be the development of bedside quick, easy to perform, cheap and effective kit which can be used to detect rotavirus for proper diarrhoea management. There is no risk whatsoever associated with participating in this study.

Where is the study run from?
The study is run by the Virology and Molecular Biology Research Group of the Obafemi Awolowo University, Ile-Ife and will take place at Obafemi Awolowo University Teaching Hospital (OAUTHC), Ile-Ife and its attached complex elsewhere, exclusively for children, called OAUTHC Comprehensive Health complex, Eleyele, Ile-Ife (Nigeria)

When is the study starting and how long is it expected to run for?
September 2020 to August 2023

Who is funding the study?
European and Developing Countries Clinical Trials Partnership (EDCTP) (Netherlands)

Who is the main contact?
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Contact information

Type(s)
Principal investigator

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Additional identifiers

Protocol serial number
ERC/2021/04/12

Study information

Scientific Title
Diarrhoea management through the development of nanoparticle-based rotavirus diarrhoea diagnostic kits and viral diarrhoea awareness

Acronym
TMA2019CDF-2731

Study objectives
The study aims are to:
1. Develop a cheap, rapid nanotechnology-based rotavirus Group A (RVA) kit to help clinicians in prompt RVA diarrhoea diagnosis, improve diarrhoea management and reduce the indiscriminate use of antibiotics in children
2. Determine the prevalence of diarrhoea in a case-control RVA epidemiological study using commercial ELISA, PCR and the developed kit in order to assess the diagnostic accuracy of the developed kit
3. Determine the specificity and sensitivity of the developed kit in comparison with that of the commercial ELISA and PCR in the RVA epidemiological study
4. Find out the environmental, clinical/risk factors and seasonal patterns associated with diarrhoea incidence in the study population and if these factors can be used to control diarrhoea prevalence by strengthening preventive methods

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 26/04/2021, Obafemi Awolowo University Teaching Hospital (OAUTHC) Ethics and Research Committee (ERC) (Ile-Ife, Nigeria; +234 (0)8152092751, +234 (0)8152092755, +234 (0) 8152092999; oauthcethicalcommittee@yahoo.com), ref: IRB/IEC/0004553

Primary study design
Observational

Study design
Observational longitudinal case-control study

Study type(s)
Diagnostic

Health condition(s) or problem(s) studied
Rotavirus Group A (RVA) diarrhoea

Interventions

This study involves the collection of stool samples from children (0-5 years) presenting with diarrhoea in Ile-Ife in the southwestern part of Nigeria. Controls (children without diarrhoea for the past 14 days) will also be obtained from children in the same age group and attending the same hospital for the purpose of vaccination. A rotavirus diagnostic kit will be developed using nanotechnology involving lactoferrin (LF), magnesium chloride, silicon, and monoclonal antibody to the VP6 gene, a group-specific antigen found in all RV that cause disease in humans. Rotavirus will be detected by serology (ELISA) and molecular methods. Sociodemographic, environmental /clinical/risk factors associated with diarrhoea will also be obtained using a structured questionnaire. To access the diagnostic accuracy of the developed kit, ELISA and PCR RVA positive and negative samples will be tested using the nanoparticle kit and the sensitivity /specificity of these methods will be compared. Thereafter, findings from this research will be used to carry out a community/media campaign against RVA diarrhoea.

Intervention Type
Other

Primary outcome(s)
RVA detected using ELISA, PCR and the developed nanoparticle-based RVA kit at the end of 1-year sample collection

Key secondary outcome(s)
Sociodemographic, environmental/clinical/risk factors associated with diarrhoea assessed using a structured questionnaire during the 1-year study period

Completion date
30/08/2023

Eligibility

Key inclusion criteria
Cases:
1. Children (aged 0 to 60 months)
2. Acute diarrheal episode (diarrhoea will be defined as three or more loose stools in the last 24 hours with or without other symptoms such as fever, vomiting or dehydration and the onset must be within the last 7 days)

Controls:
1. Healthy children coming to the same hospital/health centre for routine immunization and not presenting with gastroenteritis symptoms for the past 14 days

Participant type(s)
Healthy volunteer, Patient

Healthy volunteers allowed
No

Age group
Child

Lower age limit

0 Months

Upper age limit
60 Months

Sex
All

Total final enrolment
186

Key exclusion criteria
Cases:
1. Children who do not have diarrhoea
2. Children older than 5 years
3. Parents or guardians do not give formal consent to participate in the study

Controls:
1. Sick children
2. Children older than 5 years
3. Parents or guardians do not give formal consent to participate in the study

Date of first enrolment
21/06/2021

Date of final enrolment
20/06/2022

Locations

Countries of recruitment
Nigeria

Study participating centre
Obafemi Awolowo University Teaching Hospital
Phase 3
Ile-Ife
Nigeria
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Sponsor information

Organisation
Obafemi Awolowo University

ROR
https://ror.org/04snhqa82

Funder(s)

Funder type
Research organisation

Funder Name
European and Developing Countries Clinical Trials Partnership

Alternative Name(s)
The European & Developing Countries Clinical Trials Partnership, The European & Developing Countries Clinical Trials Partnership (EDCTP), European and Developing Countries Clinical Trials, Le partenariat Europe-Pays en développement pour les essais cliniques, A Parceria entre a Europa e os Países em Desenvolvimento para a Realização de Ensaios Clínicos, EDCTP

Funding Body Type
Private sector organisation

Funding Body Subtype
International organizations

Location
Netherlands

Results and Publications

Individual participant data (IPD) sharing plan
The dataset will not be made available to the public as part of the confidentiality agreement during the ethics application to ensure confidentiality and protection of individual data. Hence, key linking codes to the subject name will be used and data will be stored in encrypted form in a dedicated computer which is passworded. The PI and data manager have access to the code. Hard copies of collected data and forms are in a secured cabinet with limited access to individuals (Principal investigator and data manager). Raw data will not be available to the public, but results will be reported in aggregates in scientific journals or meetings without reference or links to the subjects. Data will be destroyed after 5 years

The data on the questionnaire is imputed on the dedicated system as samples are collected and results will be imputed on the same PC against each child’s code as soon as stool analysis results are available. Questionnaires are identified with the given code numbers matched with the sample bottles for each child, to further avoid misrepresentation, ensure confidentiality and keep all personal information collected during the study confidential. Each sample has the same code with the filled questionnaire and informed consent and subject information forms filled by the parent/guardian for proper documentation. A dedicated computer is used for inputting the

data, using the key linking codes. A data manager is responsible for inputting the data on the questionnaire in the private computer which is password protected, with the PI and data manager having access to the code. Also, to avoid data loss, the data is uploaded to Google Drive and updated regularly. Hard copies of collected data and forms are in a secured cabinet with limited access to individuals (principal investigator and data manager). Raw data will not be available to the public but results will be reported in aggregates in scientific journals or meetings without reference or links to the subjects.

IPD sharing plan summary

Not expected to be made available

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		17/07/2025	26/09/2025	Yes	No
Study website	Study website	11/11/2025	11/11/2025	No	Yes